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UMO 1561.1
04UMC007

Application of: Gabor Forgacs et al.

Art Unit: 1653

Serial No.: 10/590,446

Filed: October 10, 2007

Confirmation No.: 8467

For: SELF-ASSEMBLING CELL AGGREGATES AND METHODS OF MAKING
ENGINEERED TISSUE USING THE SAME

Examiner: Srivastava, Kailash C.

November 27, 2011

Agenda for Telephone Interview – For Discussion Only

Via Facsimile – (571) 273-0923

TO THE COMMISSIONER FOR PATENTS,
SIR:

Applicants thank the Examiner and his Supervisor in advance for the courtesy of granting a telephone interview, scheduled for Monday, November 28, 2011, at 1:00 P.M. Eastern time, to discuss issues raised in the Office Action issued September 1, 2011. Applicants would like to discuss the items outlined below during the interview.

I. Proposed Amendment to Independent Claim 52

Applicants propose amending independent claim 52 as follows:

52. (currently amended) A three-dimensional layered structure comprising: at least one layer of a matrix; and a plurality of cell aggregates, each cell aggregate comprising a plurality of living cells; wherein the cell aggregates are embedded in the at least one layer of matrix in a non-random predetermined pattern, the cell aggregates having predetermined positions in the pattern, the positions allowing at least one aggregate of said plurality of cell aggregates to fuse with at least one other aggregate of the plurality of cell aggregates.

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II. Rejection of claims 52–53, 56, 58, and 61–63 under 35 U.S.C. § 102(b) as anticipated by Tang et al. (JACS, 125:12988–89, 2003)

As an initial matter, Applicants respectfully request clarification as to the Examiner's position regarding the teachings of Tang et al. It is not entirely clear to Applicants whether the Examiner's reasoning is:

- (A) that Tang et al. describes suspending cell aggregates in collagen; or
- (B) that the hexagonal structures shown in Figure 2A of Tang et al. are "cell aggregates."

Applicants respectfully submit that in either case, independent claim 52, amended as proposed herein, is not anticipated by Tang et al. If the Examiner's position is that Tang et al. describes suspending cell aggregates in collagen, Applicants note that Tang et al. states that human fibroblasts (not aggregates of fibroblasts) were suspended in collagen (see the first full paragraph under Figure 1 on page 12988). Furthermore, even if some aggregates of cells were present when suspended in the collagen or to the extent that cell aggregates might form over time in the collagen gels, such aggregates clearly would not be embedded in the gel in a non-random, predetermined pattern, as required by claim 52.

If, on the other hand, the Examiner's position is that the hexagonal structures shown in Figure 2A of Tang et al. are "cell aggregates," Applicants respectfully submit that these hexagonal structures do not have "positions allowing at least one aggregate of said plurality of cell aggregates to fuse with at least one other aggregate of the plurality of cell aggregates," as required by claim 52, amended as proposed herein.

III. Rejection of claims 52–53, and 56–66 under 35 U.S.C. § 103(a) as having been obvious from Tang et al. in view of Boland et al. (U.S. Patent Application Publication No. 2004/0237822).

Applicants respectfully submit that the Examiner has not presented sufficient rationale for his obviousness arguments. M.P.E.P § 2141.III. states that "rejections on

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obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In particular, it is not clear what modifications are being made in combining the references.

Applicants further respectfully submit that Boland et al. does not cure the deficiencies of Tang et al.

IV. Rejection of claims 54–55 under 35 U.S.C. § 103(a) as having been obvious from Tang et al. in view of Boland et al., and further in view of Mizumoto et al. (*Cryotechnology* 31:69–75, 1999)

Applicants respectfully submit that Mizumoto et al. does not overcome the deficiencies of Tang et al. and Boland et al., and furthermore that the Examiner has not provided a reason why a skilled artisan would have combined Mizumoto et al. with the other references.

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CONCLUSION

In view of the above, Applicants do not believe that any further amendments to the claims are necessary.

Respectfully submitted,

Elizabeth Millard

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